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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,032	05/10/2006	Sei Kwang Hahn	HAHN5	3877

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,032	HAHN ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *9, 11, 20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10, 12-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6 pgs / 10 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is the national stage entry of PCT/JP04/16948, filed 15 Nov 2004; and claims benefit of foreign priority documents JAPAN 2003-385054, filed 14 Nov 2003; JAPAN 2003-407681, filed 05 Dec 2003; and JAPAN 2004-259157, filed 07 Sep 2004; currently an English language translation of these foreign priority documents have not been filed.

Claims 1-22 are pending in the current application. Claims 9, 11, 20 and 22, drawn to non-elected species, are withdrawn. Claims 1-8, 10, 12-19 and 21 are examined on the merits herein.

Response to Remarks

Examiner acknowledges receipt of certified copies of foreign priority documents JAPAN 2003-385054, filed 14 Nov 2003; JAPAN 2003-407681, filed 05 Dec 2003; and JAPAN 2004-259157, filed 07 Sep 2004, filed under section 119 (a)-(d).

Election/Restrictions

Applicant's election with traverse of the species of in the reply filed on 21 Feb 2008 is acknowledged. The traversal is on the ground(s) that Applicants assert that Russell-Jones does not anticipate all of Applicants' generic claims. This is not found persuasive because Russell-Jones et al. discloses the polysaccharide carboxymethyl cellulose as a crosslinked particle prepared by solvent evaporation, in which the dispersed solution forms microparticulate droplets in the process of evaporation, and

the solution in said droplets is concentrated during said evaporation. Therefore the common feature is a known product, and not the special technical feature of a single general inventive concept.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9, 11, 20 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 21 Feb 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 12 and 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "dilute" in claims 1, 7, 12 and 18 is a relative term which renders the claims indefinite. The term "dilute" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The relative term "dilute" may refer to almost any concentration, for example a solution that is saturated is a compound is "dilute" compared to a solution that is super-saturated in

said compound. The specification does not provide a definition of what concentration, such as % by weight or molarity, is meant by the term "dilute".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 10, 12-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell-Jones et al. (US Patent 6,221,397, issued 24 Apr 2001, provided by Applicant in IDS filed 10 May 2006).

Russell-Jones et al. discloses the formulation of crosslinked particles entrapping a pharmaceutical agent (column 2, lines 30-49). Russell-Jones et al. discloses process of dispersing the solution of a compound in a first solvent into a non-miscible solvent and evaporating off the first solvent (column 6, lines 46-54). During this evaporating process the first solvent dispersed in the non-miscible solvent forms microparticulate droplets, and the concentration of soluble compounds within these microparticulate droplets of the first solvent becomes concentrated. Russell-Jones et al. discloses the process wherein the particles are formed by the crosslinking reaction of a thiol group, or mercapto group, with a carboxyl group, or the unsaturated bond of the carbonyl in a carboxyl group (column 7, lines 43-44). Therefore the process disclosed by Russell-Jones et al. meets the limitations of instant claims 1 and 10. Russell-Jones et al.

discloses the particles made of hyaluronic acid (column 7, line 65), meeting the limitations of instant claim 2. Russell-Jones et al. discloses particle size may vary between 10 nm, or 0.01 micrometers, and 900 micrometers, specifically disclosing the diameter of 10 micrometers (column 6, lines 13-14 and 20-22), meeting the limitations of instant claim 4. Russell-Jones et al. discloses the particles for controlled release, or sustained-release, of a pharmaceutical agent (abstract), meeting the limitations of instant claims 5 and 6. Russell-Jones et al. discloses the pharmaceutical agent incorporated into the particle at the time of the formation of the particle, by including the pharmaceutical agent within the mixture of components required to produce the particle (column 11, lines 25-28), meeting the limitations of instant claim 7. Russell-Jones et al. discloses the particle which reduces or eliminates modification of the pharmaceutical agent (column 2, lines 30-35), specifically the modification due to the crosslinking reaction (column 2, lines 14-17), meeting the limitations of instant claim 8. Russell-Jones et al. discloses the particle made by said process, meeting the limitations of instant claims 12-18 and 21.

Claims 12-19 and 21 recite a product-by-process. It is apparent from what is disclosed that the product disclosed by Russell-Jones et al. is made by an identical or substantially identical process as the product of instant claims 12, 13, 15-19 and 21. It is apparent from what is disclosed that the product disclosed by Russell-Jones et al. is identical or substantially identical to the product of instant claim 14. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not

depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Claims 1-8 and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Illum et al. (US Patent Application Publication 2001/000765, published 12 Jul 2001, provided by Applicant in IDS filed 10 May 2006).

Illum et al. discloses a drug incorporated into polysaccharide microspheres prepared by spray drying (page 2, paragraph 22). Illum et al. discloses the polysaccharide solution includes cross-linking agents (page 4, paragraph 43). Illum et al. discloses the spray drying process to atomize the polysaccharide solution into microparticulate droplets, followed by drying, or concentrating the solution in the droplets (page 3, paragraph 35), meeting the limitations of instant claims 1 and 3. Illum et al. discloses the use of the polysaccharide hyaluronic acid (page 4, paragraph 39),

meeting the limitations of instant claim 2. Illum et al. discloses the method of making said microspheres wherein the resulting particle size is from 0.1 to 10 micrometers (page 4, paragraph 44), meeting the limitations of instant claim 4. Illum et al. discloses the method wherein the microsphere is a sustained-release drug carrier (page 4, paragraphs 40 and 41), meeting the limitations of instant claims 5 and 6. Illum et al. discloses the process of preparing a dilute solution, 0.75 - 3 g polysaccharide per 20 mL solution, containing the polysaccharide and drug (page 3, paragraph 34), prior to the crosslinking reaction, indicating the crosslinking does not cause drug denaturation, meeting the limitations of instant claims 7 and 8. Illum et al. discloses the polysaccharide microspheres made by said process, meeting the limitations of instant claims 12-19.

Claims 12-19 recite a product-by-process. It is apparent from what is disclosed that the product disclosed by Illum et al. is made by an identical or substantially identical process as the product of instant claims 12-19. However, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic

acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Claims 1-6 and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (US Patent Application Publication 2003/0211166, published 13 Nov 2003, cited in PTO-892).

Yamamoto et al. discloses microspheres of hyaluronic acid to deliver a drug or active substance (page 2, paragraphs 27 and 28). Yamamoto et al. discloses the microspheres prepared by standard spray drying techniques, in which a solution comtaining the hyaluronate polymer is dispersed to form atomized, or microparticulate, droplets which condense and dry, concentrating the solution (page 2, paragraph 29). Yamamoto et al. discloses chemical cross-linking of the microspheres co-formulated into the microspheres, added to the starting hyaluronic acid starting material or after fabrication in the partially hydrated state (page 2, paragraph 30). Yamamoto et al. discloses using a starting solution containing 0.5% concentration HA, or a dilute solution (page 3, paragraph 37). This can be interpreted as the dilute solution, the starting material, containing hyaluronic acid having crosslinkable functional groups, and the crosslinking reaction occurring after fabrication, the dispersing to form atomized or microparticulate droplets, and during the concentrating of the solution during the

condensing and drying of the partially hydrated state, meeting the limitations of instant claims 1-3 and 5. Yamamoto et al. discloses the microparticles produced by said method, meeting the limitations of instant claims 12-14 and 16. Yamamoto et al. discloses the process and product wherein the microspheres have a diameter between 0.01 and 100 microns, meeting the limitations of instant claims 4 and 15. Yamamoto et al. discloses the process and product wherein the microspheres are capable of providing a sustained drug delivery effect (page 3, paragraph 36), meeting the limitations of instant claims 6 and 17. Yamamoto et al. discloses drugs or other active agents encapsulated in the microsphere to provide local drug delivery (page 3, paragraph 35). It is apparent from what is disclosed that said microsphere encapsulating a drug or other active agent, which is still active or not denatured, disclosed by Yamamoto et al. is a substantially identical product as what is claimed in instant claim 18 and 19, therefore said microsphere encapsulating a drug or other active agent meets the limitations of instant claims 18 and 19.

Claims 12-19 recite a product-by-process. It is apparent from what is disclosed that the product disclosed by Yamamoto et al. is made by an identical or substantially identical process as the product of instant claims 12-17. It is apparent from what is disclosed that the product disclosed by Yamamoto et al. is identical or substantially identical to product of instant claims 18 and 19. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 8, 10, 18, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (US Patent Application Publication 2003/0211166, published 13 Nov 2003, cited in PTO-892) in view of Schense et al. (US Patent Application Publication 2003/0012818, 16 Jan 2003, cited in PTO-892).

Yamamoto et al. discloses as above.

Yamamoto et al. does not disclose the specific method wherein the dilute solution before the crosslinking reaction contains a drug, and the drug is held in the microparticles obtained after the crosslinking reaction (instant claim 7). Yamamoto et al. does not disclose the specific method wherein the crosslinking reaction does not cause drug denaturation even in the presence of the drug (instant claim 8). Yamamoto et al. does not disclose the specific method wherein the specific crosslinking reaction is a reaction in which crosslinkages are formed by addition reaction between a mercapto group and an unsaturated bond (instant claim 10). Yamamoto et al. does not disclose the specific microparticle wherein the crosslinking reaction is a reaction in which crosslinkages are formed by addition reaction between a mercapto group and an unsaturated bond (instant claim 21).

Schense et al. teaches bioactive molecules entrapped within a matrix for the controlled delivery of said bioactive molecules wherein said bioactive molecules are exntrapped during gelation of the matrix (page 1, paragraph 12). Schense et al. teaches the matrix formed by the reaction of a multi-thiol, or mercapto groups, and a

conjugated unsaturated group, or unsaturated bond, in a solution that contains a bioactive molecule, or drug, mixed together to perform the crosslinking reaction (page 6, paragraphs 81 and 82). Schense et al. teaches the matrix-forming reaction is self-selective, meaning the thiol preferentially reacts with the conjugated unsaturated group rather than other biological compounds such as the bioactive molecule, indicating that the matrix-forming reaction does not cause drug denaturation (page 3, paragraphs 26 and 27). Schense et al. does not explicitly describe the gelation or matrix-forming reaction as a crosslinking reaction, however, one of ordinary skill in the art would understand the terms gelation and matrix to refer to the forming of a crosslinked polymer, as described in page 3 paragraphs 29 and 30. Schense et al. teaches the matrix made of natural polymers such as hyaluronic acid (page 3, paragraph 39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Yamamoto et al. and Schense et al. Both the invention of Yamamoto et al. and the invention of Schense et al. are drawn to crosslinked hyaluronic acid for sustained release of a bioactive molecule. Schense et al. teaches the invention of Schense et al. increases the retainable concentration of bioactive molecules in a matrix (page 1, paragraph 9). One of ordinary skill in the art at the time of the invention would be motivated to combine the invention of Yamamoto et al. with the teaching of Schense et al. to improve a similar product and process in the same way to achieve predictable results because of the teaching of Schense et al. that the invention of Schense et al. increases the retainable concentration of bioactive molecules in a matrix.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-14, 16-19 and 21 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 10, 17, 26, 27, 29-32, 35, 36 and 38-41 of copending Application No. 10/536031. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both instant claims 12-14, 16-19 and 21 and claims 1, 10, 17, 26, 27, 29-32, 35, 36 and 38-41 of copending Application No. 10/536031 are drawn to a sustained-release drug carrier comprising

hyaluronic acid crosslinked by the reaction of a mercapto group and an unsaturated bond. The incorporation of the instant invention into a pharmaceutical composition is suggested in the instant specification, page 32 lines 10-17.

Instant claims 12-14, 16-19 and 21 are drawn to a product-by-process. However, as recited above, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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